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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/940,919	08/28/2001	Carl Johan Friddle	LEX-0228-USA	5149

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EXAMINER	
WEGERT, SANDRA L	
ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 04/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/940,919	FRIDDLE ET AL.	
	Examiner	Art Unit	
	Sandra Wegert	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 4-7* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2/4/02 8/28/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Detailed Action

Status of Application, Amendments, and/or Claims

The Preliminary Amendment, submitted 29 December 2003, and the two Information Disclosure Statements, submitted 4 February 2002 and 28 August 2002, respectively, have been entered into the record. Applicant's election of Invention I (Claims 1 and 2), in the paper of 29 December 2003, is acknowledged. Claim 3 has been cancelled. Claims 4-7 have been entered and read on the elected Invention.

Claims 1, 2 and 4-7 are under examination in the Instant Application.

Claim Rejections/Objections

Claim Rejections - 35 USC § 101 and 35 USC § 112, first paragraph

The following is a quotation of 35 U.S.C. 101:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2 and 4-7 are rejected under 35 U.S.C. 101 because the claimed invention lacks a credible, specific and substantial asserted utility or a well-established utility.

The claims are directed to a nucleotide of SEQ ID NO: 1, which encode a polypeptide of 525 amino acids (SEQ ID NO: 2). Further claim limitations are presented to isolated nucleic acids which hybridize to SEQ ID NO: 1 or its complement. Claims are also presented encompassing vectors and cells comprising the nucleic acid of SEQ ID NO: 1. However, the specification does not disclose a function for the nucleotide of SEQ ID NO: 1, encoding the polypeptide of SEQ ID NO: 2, in the context of the cell or organism.

No well-established utility exists for newly isolated complex biological molecules. However, the specification implies that the following are credible, specific and substantial patentable utilities for the claimed putative polynucleotide and the polypeptide encoded by the claimed polynucleotide:

1) To make hybridization probes to detect the polynucleotide of SEQ ID NO: 1.

2) To produce the polypeptide of SEQ ID NO: 2.

3) In assays to screen for compounds capable of modifying the interaction between receptor and ligand.

4) For making antisense oligonucleotides.

5) For use in the construction of "knock-in" or "knock-out" organisms.

6) To make antibodies to the polypeptide encoded by the polynucleotide of SEQ ID NO:1.

7) In tissue typing (Specification, page 3).

Each of these shall be addressed in turn:

1) To make hybridization probes to detect the polynucleotide of SEQ ID NO: 1.

This asserted utility is credible but not substantial or specific. Hybridization probes and primers can be designed from any polynucleotide sequence. Further, the specification does not disclose specific cDNA, DNA, or RNA targets. Since this asserted utility is not present in mature form, so that it could be readily used in a real world sense, the asserted utility is not substantial.

2) To produce the polypeptide of SEQ ID NO: 2. This asserted utility is also credible and substantial, but not specific. Many nucleotide sequences can be used to make polypeptides. However, if the specification discloses nothing specific and substantial about either the polynucleotides or the polypeptides, both the polynucleotides and polypeptides produced have no patentable utility.

3) In assays to screen for compounds capable of modifying the interaction between receptor and ligand. This asserted utility is also credible and substantial but not specific. Such assays can be performed for any receptor-ligand pair. Additionally, the specification discloses nothing specific or substantial for the compounds or receptors that can be identified by this method.

4) For making antisense oligonucleotides. This asserted utility is credible but not specific or substantial. Such can be performed for any polynucleotide. Further, the specification does not disclose diseases or conditions associated with the claimed polynucleotide. Significant further experimentation would be required of the skilled artisan to identify individuals in need of antisense treatment to determine the route of administration of the antisense, as well as gene targets and quantity and duration of treatment. Since this asserted utility is also not presented in

mature form, so that it could be readily used in a real world sense, the asserted utility is not substantial.

5) For use in the construction of "knock-in" or "knock-out" organisms. This asserted utility is credible but not specific or substantial. The specification does not disclose diseases associated with a mutated, deleted, or translocated gene comprising SEQ ID NO: 1. Significant further experimentation would be required of the skilled artisan to identify any such a disease. The specification discloses nothing about the phenotypic result when the gene associated with SEQ ID NO: 1 is "knocked in" or "knocked out," nor what specific tissues and cells are being targeted. Since this asserted utility is not present in mature form, so that it could be readily used in a real world sense, the asserted utility is not substantial.

6) To make antibodies to the polypeptide encoded by the polynucleotide of SEQ ID NO:1. This asserted utility is credible and substantial, but not specific. Antibodies can be made to any polypeptide. However, if the specification discloses nothing specific and substantial about the polypeptide, then the polypeptide, the polynucleotide encoding the polypeptide and antibodies have no patentable utility.

7) In tissue typing. This asserted utility is credible but not substantial or specific. Such assays can be performed with any polypeptide encoded by a polynucleotide; thus, the asserted utility is not specific. Furthermore, the specification discloses a wide range of tissues that express the polypeptide of SEQ ID NO: 2 (Specification, page 3, line 23). Applicant implies that this expression pattern supports a useful function of the polynucleotide encoding the polypeptide of SEQ ID NO: 2. However, patentable utility of tissue typing for the claimed polynucleotide encoding the disclosed polypeptide is not substantial, because one skilled in the art would not

readily use the nucleotide sequences for tissue-typing in a real world sense as the protein is not specific to one tissue and is not associated with any disease or disorder. This asserted utility is also not specific because numerous unrelated nucleotide sequences would also show a similar tissue-typing pattern. In addition, evidence of mere expression in a tissue is not tantamount to a showing of a role for the polynucleotide of the present invention. It is not clear if expression of the polynucleotide of the present Invention is correlated with a specific change in physiology, for example, or with a disease state. Since this asserted utility is also not present in mature form, so that it could be readily used in a real world sense, the asserted utility is not substantial.

Claims 1, 2 and 4-7 are also rejected under the Enablement provision of 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. SEQ ID NO: 1 appears to encode a polypeptide comprised of fragments from several unrelated molecules: nucleotides 10-129 encode *hypothetical protein* BAC99476 from rice (Sasaki, et al, 2003, Accession No. BAC99476); nucleotides 170-268 bear closest homology to a portion of Methylenetetrahydrofolate dehydrogenase 1 (Strausberg, et al, 2003, Accession No. AAH50420); nucleotides 352-528 appear to encode a portion of a mycobacterial protein (Garnier, et al, 2003, Accession No. CAD97189); and finally, nucleotides 580-699 encode a protein which resembles (at 30% homology) a portion of a vesicular amino acid transporter (Strausberg, et al, 2003, Accession No. AAH53582).

Due to the large quantity of experimentation necessary to determine an activity or property of the disclosed polypeptide such that it can be determined how to use the claimed polynucleotides encoding SEQ ID NO: 2 and to screen for activity, the lack of direction/guidance presented in the specification regarding same, the absence of working examples directed to same, the complex nature of the invention, the state of the prior art establishing that biological activity cannot be predicted based on structural similarity, and the breadth of the claims which fail to recite particular biological activities, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> **The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.**

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rendered indefinite because of the phrase "stringent conditions," which is a conditional term. In other words, for example, some nucleic acids which are able to hybridize under stringent conditions would be unable to hybridize under non-stringent conditions. The metes and bounds of the claim, therefore, cannot be ascertained. This rejection can be overcome by supplying specific conditions supported by the specification, which the Applicants consider "stringent," or by removing the indefinite phrase.

Conclusion: Claims 1, 2 and 4-7 are rejected for the reasons recited above.

Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Wegert whose telephone number is (571) 272-0895. The examiner can normally be reached Monday - Friday from 9:00 AM to 5:00 PM (Eastern Time). If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached at (571) 272-0887.

The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SLW
4/22/04

Elizabeth C. Kemmerer

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PRIMARY EXAMINER